# PATENT COOPERATION TREATY REC'D 1 4 JUL 2004

**PCT** 

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### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applio			ent's file reference	FOR FURTHER A	CTION	See Notificat Preliminary E	ion of Transmittal of International Examination Report (Form PCT/IPEA/416)	
1		al app 03/04	lication No. 649	International filing date	(day/mon		Priority date (day/month/year) 12.04.2002	
Intern A230			ent Classification (IPC) or bo	th national classification	and IPC			
Applic MEIJ		AIRIE	S CORPORATION					
1.	This Auth	internority	national preliminary exam and is transmitted to the	ination report has becapplicant according to	en prepar Article 3	red by this Int 6.	ernational Preliminary Examining	
2.	This	REP	ORT consists of a total of	5 sheets, including t	his cover	sheet.		
H	⊠	nee	report is also accompani n amended and are the b Rule 70.16 and Section	asis for this renort and	i <i>l</i> or sheel	e containing	ion, claims and/or drawings which have rectifications made before this Authority the PCT).	
	Thes		nexes consist of a total of					
з.	This	repor	t contains indications rela	ting to the following it	ems:			
ı		$\boxtimes$	Basis of the opinion	_				
1	11		Priority					
1	Ш			inion with regard to n	oveltv. in	vantive sten s	and industrial applicability	
1	V		Lack of unity of invention		Ovo.ty,	venuvo otop t	and industrial applicability	
١	<b>V</b>	☒	<u>-</u>	der Rule 66.2(a)(ii) wi	th regard	to novelty, in	ventive step or industrial applicability;	
-	•		Certain documents cited			•		
			Certain defects in the int					
١	/III		Certain observations on	the international appli	cation		- · · ·	
Date of	subn	nissior	of the demand		Date of c	ompletion of th	is report	
12.09.	2.09,2003				13.07.2	2004		
Name a	ame and mailing address of the international reliminary examining authority:				Authorized Officer			
<u></u>		Euro D-80 Tel.	pean Patent Office 1298 Munich 149 89 2399 - 0 Tx: 523656 149 89 2399 - 4465	epmu d	Baming Telephon	er, U e No. +49 89 2	399-2176	

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP 03/04649

I. E	Basis	of the	report
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1. With regard to the **elements** of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

	De	scription, Pages	
	1-3	3, 5-32	as originally filed
	4		received on 21.04.2004 with letter of 19.04.2004
	Cla	aims, Numbers	
	1-1	0	received on 21.04.2004 with letter of 19.04.2004
	Dra	awings, Sheets	
	5/9	-9/9	as originally filed
	1/9	-4/9	received on 30.12.2003
2.	Wit lan	th regard to the <b>langu</b> guage in which the int	age, all the elements marked above were available or furnished to this Authority in the ternational application was filed, unless otherwise indicated under this item.
	The	ese elements were av	ailable or furnished to this Authority in the following language: , which is:
		the language of a tra	unslation furnished for the purposes of the international search (under Rule 23.1(b)).
			ication of the international application (under Rule 48.3(b)).
	□	the language of a tra Rule 55.2 and/or 55.	nslation furnished for the purposes of international preliminary examination (under 3).
3.	Wit inte	h regard to any <b>nucle</b> rnational preliminary (	otide and/or amino acid sequence disclosed in the international application, the examination was carried out on the basis of the sequence listing:
		contained in the inter	rnational application in written form.
		filed together with the	e international application in computer readable form.
		furnished subsequer	ntly to this Authority in written form.
		furnished subsequen	itly to this Authority in computer readable form.
		The statement that the international approximation of the international approximation of the statement of th	ne subsequently furnished written sequence listing does not go beyond the disclosure oplication as filed has been furnished.
		The statement that the listing has been furni	ne information recorded in computer readable form is identical to the written sequence shed.
4.	The	amendments have re	esulted in the cancellation of:
		the description,	pages:
		the claims,	Nos.:
		the drawings,	sheets:

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International application No.

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5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

see separate sheet

- 6. Additional observations, if necessary:
- V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

Novelty (N)

Yes: Claims

1-10

No: Claims

Inventive step (IS)

Yes: Claims

No: Claims

1-10

Industrial applicability (IA)

Yes: Claims

1-10

No: Claims

2. Citations and explanations

see separate sheet



#### Re Item I

#### Basis of the opinion

The amendments to p. 25 and 22 filed with letters of 30.12.03 and 19.4.04 respectively go beyond the disclosure of the international application as filed (Art. 34(2)(b)). It is not clear on which basis these contradicting amendments/corrections to tables 4 and 7 are performed. Therefore these amendments are not allowed.

#### Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: WO 01 88150 A (GERMOND JACQUES EDOUARD ; MOLLET BEAT (CH); NESTLE SA (CH)) 22 November 2001 (2001-11-22) cited in the application
- D2: EP-A-1 112 692 (MEIJI MILK PRODUCTS COMPANY LT ; WAKAMOTO PHARMA CO LTD (JP)) 4 July 2001 (2001-07-04) cited in the application & JP 2001 000143 A 9 January 2001 (2001-01-09)
- D3: PATENT ABSTRACTS OF JAPAN vol. 2000, no. 16, 8 May 2001 (2001-05-08) & JP 2001 002578 A (KOGA YASUHIRO; MEIJI MILK PROD CO LTD: WAKAMOTO PHARMACEUT CO LTD), 9 January 2001 (2001-01-09)
- D4: US 2002/037341 A1 (LEE JEONG JUN ET AL) 28 March 2002 (2002-03-28)
- D5: WO9827825
- 5.1 The subject-matter of claim 1 is novel (Art. 33 (2) PCT) in view of the documents available to the examiner.

The same applies mutatis mutandis to the independent claims 5 and 6.

5.2 For the purpose of examining the inventive step of claim 1, D2 can be regarded as

### INTERNATIONAL PRELIMINARY

International application No. PCT/JP 03/04649

**EXAMINATION REPORT - SEPARATE SHEET** 

the closest prior art.

D2 (cf. ex. 1 and 2 and claims) discloses a food or drink product such as a fermented milk or yoghurt with a disinfecting property against Helicobacter pylori comprising Lb. gasseri OLL 2716.

D2 therefore differs with the present application in that a cheese comprising Lb. gasseri is not disclosed.

The problem to be solved by the present application therefore lies in the provision of an alternative milk product comprising Lb. gasseri with a disinfecting potency against Helicobacter pylori.

The solution over D2 found in claim 1 of the present application is the preparation of a cheese instead of a yoghurt or acid milk. D1 (claims 2 and 9) discloses a cheese comprising Lactobacillus gasseri, without giving an indication that this organism has a disinfection potency against Helicobacter pylori. D1 (cf. p. 5, lines 24-28 and claims) and D4 (claims 1 and 4) give clear indications that it is possible to prepare a cheese comprising very closely related lactobacilli of the acidophilus group (Lb. johnsonii in D1 and Lb. acidophils in D4) with such an effect (displacing Helicobacter in D1 and inhibiting growth of Helicobacter in D4). Therefore claim 1 can not be considered inventive according to Art. 33 (3) PCT.

The same applies mutatis mutandis to the independent claim 5. As for independent claim 6, D5 (cf. claims 1, 3, 4) discloses a process for production of a cheese wherein yeast extract is added to pasteurised milk before fermentation with Lb. johnsonii, as a result of which a curd is formed.

5.3 A positive preliminary examination report for the dependent claims can not be established since the requirements of the PCT concerning inventive step for the independent claims are not complied with.



#### CLAIMS

- 1. Natural cheese which comprises a lactic acid bacterium belonging to Lactobacillus gasseri having a disinfection potency against Helicobacter pylori.
- 2. The natural cheese according to claim 1, wherein the lactic acid bacterium is resistant to low pH environment.
- 3. The natural cheese according to claim 1 or 2, wherein the lactic acid bacterium is *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) or a mutant thereof.
- 4. The natural cheese according to any of claims 1 to 3, wherein the lactic acid bacterium is present at a viable count of 10<sup>7</sup> cfu/g or more when preserved at a temperature of 10°C or less for 6 months.
- 5. A food which comprises the natural cheese -according to any one of claims 1 to 4.
- 6. (Amended) A process for producing the natural cheese according to any one of claims 1 to 4, which comprises:



adding an yeast extract to a milk component before formation of a curd.

- 7. The process according to claim 6, wherein the curd is incubated without being cooled after molding and pressing.
- 8. The process according to claim 6 or 7, wherein the curd is incubated at 20 to  $35^{\circ}$ C for 16 to 26 hours.
- 9. The process according to any one of claims 6 to 8, wherein a lactic acid bacterium belonging to Lactobacillus gasseri having a disinfection potency against Helicobacter pylori is added to raw milk as a starter.
- 10. The process according to any one of claims 6 to 9, wherein the lactic acid bacterium is *Lactobacillus* gasseri OLL 2716 (FERM BP-6999) or a mutant thereof.



The present invention relates to the following (1) to (8):

- (1) Natural cheese which comprises a lactic acid bacterium belonging to Lactobacillus gasseri having a disinfection potency against Helicobacter pylori.
- (2) The natural cheese according to (1), wherein the lactic acid bacterium is resistant to low pH environment.
- (3) The natural cheese according to (1) or (2), wherein the lactic acid bacterium is *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) or a mutant thereof.
- (4) The natural cheese according to any of (1) to (3), wherein the lactic acid bacterium is present at a viable count of  $10^7$  cfu/g or more when preserved at a temperature of  $10^\circ$ C or less for 6 months.
- (5) A food which comprises the natural cheese according to any one of (1) to (4).
- (6) A process for producing the natural cheese according to any one of (1) to (4), which comprises:

adding a yeast extract to a milk component before formation of a curd.

(7) The process according to (6), wherein the curd is incubated without being cooled after molding and pressing.



problem was noticeable concerning the flavor of the gouda cheese (Table 6).

Table 4

Changes in bacterial count during the process of producing

L. gasseri OLL 2716-containing gouda cheese

	goddu cheese					
Step	L. gasseri count (log cfu/g)	Other bacteria (log cfu/g)				
Sterilized milk	-	3.48				
L. gasseri starter	9.03	_				
CHN-01 starter	-	9.03				
Raw milk with starter	6.79	6.92				
Whey	6.08	6.04				
Salt-free curd (Day produced)	8.74	9.23				
Salt-containing curd (Day following production)	8.75	9.69				

Table 5
Changes in bacterial count during preservation of
L. gasseri OLL 2716-containing gouda cheese

The concarning goods cheese									
Preservation temperature	Preservation Preserved at 10°C (log cfu/g)				Preserved at 5°C (log cfu/g)				
Sampling part	Center		Surface		Center		Surface		
Preservation time	ГG	Others	LG	Others	LG	Others	<b>LG</b>	Others	
Immediately after production-	8.75	9.69	8.74	9.67		_			
-After 1 week .	8.78	- 9.74	8.60	9.66	_		ļ <del>-</del>		
After 2 weeks	8.81	9.77	8.38	8.76	-				
After 1 month	8.60	9.04	7.78	8.73	8.78	9.62	7.78	8.73	
After 2 months	8.00	.8.60	7.10	842	. 8.60	9.20	7.48	8.70	
After 3 months	8.08	7.41	-	_	8.38	8.75	_		
After 4 months	7.60	7.04		_	8.04	8.86	_		
After 5 months	7.38	7.36	-	_	8.04	7.79			
After 6 months	7.67	6.20	<6.00	<6.00	8.01	7.30	<6.00	<6.00	

LG: L. Gasseri

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